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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/774,751

Applicant(s)

GRYCHOWSKI ET AL.

Examiner

NIHIR PATEL

Art Unit

3772

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06.24.2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14, 24-30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,4,28 and 30 is/are allowed.
- 6) ☒ Claim(s) 1,5-14, 24-27,29 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09.15.2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed June 24th, 2008, with respect to claims 1, 3-14, 24-30 and 32-35 have been fully considered and are persuasive. The previous rejection(s) of the office action dated March 24th, 2008 has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1, 9-14, 29 and 33-35** are rejected under 35 U.S.C. 102(b) as being anticipated by Kremer, Jr. (US 4,803,977).

4. **As to claims 1 and 33**, Kremer teaches an apparatus that comprises a chamber **21** (see **figure 1; col. 3 lines 15-25**) housing defining an interior space and comprising an input end (see **figure 1**) and an output end (see **figure 1**); a one way inhalation valve positioned upstream of the interior space, the one way inhalation valve **15** (see **figure 1; column 3 lines 15-25**) operative to permit a flow of gases into the interior space of the chamber housing; a first inhalation conduit **28** (see **figure 1; column 3 lines 25-35**) communicating with the output end of the chamber, the first inhalation conduit comprising an inlet communicating with the output end of the chamber housing (see **figure 1**) and an outlet adapted to transmit medication to the patient (see **figure 1; col. 3 lines 30-40**), wherein the inlet and outlet are axially aligned with the output end of the holding chamber; a second inhalation conduit communicating with the input end of the chamber

housing, wherein the one way inhalation valve is located in the second inhalation conduit (**see figure 1**), the second inhalation conduit comprising an oxygen intake line communicating with the one way inhalation valve (**see abstract**) communicating with the one way inhalation valve; an exhaust conduit **33** communicating with the first inhalation conduit at a location positioned between the inlet and the outlet of the first inhalation conduit (**see figure 1**); and a one way exhaust valve **31** located in the exhaust conduit, the one way exhaust valve adapted to prevent backflow of gas from the exhaust conduit into the first inhalation conduit (**see figure 1**; **col. 3 lines 50-60**).

5. **As to claim 9**, Kremer teaches an apparatus wherein the first inhalation conduit comprises a mask (**see column 3 lines 35-45**).
6. **As to claim 10**, Kremer teaches an apparatus that comprises an adaptor **26** connected to the output end of the chamber (**see figure 1**) housing and comprising a first portion defining at least a portion of the first inhalation conduit **25** and a second portion defining at least a portion of the exhaust conduit **33**, wherein the one way exhaust valve **31** is positioned in the second portion of the adaptor **26**, and further comprising an exhaust line connected to the second portion and defining at least a portion of the exhaust conduit (**see figure 1**).
7. **As to claim 29**, Kremer teaches an apparatus wherein the second inhalation conduit is isolated from and does not communicate with ambient air (**see col. 3 lines 45-65**).
8. **As to claim 11**, Kremer teaches an apparatus that comprises a chamber **21** (**see figure 1**; **col. 3 lines 15-25**)) housing defining an interior space and comprising an input end (**see figure 1**) and an output end (**see figure 1**); a one way inhalation valve positioned upstream of the interior space, the one way inhalation valve **15** (**see figure 1**; **column 3 lines 15-25**) operative to permit

a flow of gases into the interior space of the chamber housing; an inhalation conduit communicating with the output of the chamber, the inhalation conduit adapted to transmit medication to the patient (see col. 3 lines 35-45); an exhaust conduit 33 communicating with the first inhalation conduit; a one way exhaust valve 31 located in the exhaust conduit, the one way exhaust valve adapted to prevent backflow of gas from the exhaust conduit into the first inhalation conduit (see figure 1; col. 3 lines 50-60); and an adaptor 26 connected to the output end of the chamber housing (see figure 1) and comprising a first portion 25 defining at least a portion of the inhalation conduit and a second portion 30 defining at least a portion of the exhaust conduit 33, wherein the one way exhaust valve 31 is positioned in the second portion of the adaptor, and further comprising an exhaust line connected to the second portion and defining at least a portion of the exhaust conduit 33, wherein the first portion defines a first passageway having a first and second passageway, and wherein the adaptor further defines a third passageway communicating between the first passageway and the second passageways, wherein the one way exhaust valve is disposed in the second passageway (see figure 1).

9. **As to claim 12**, Kremer teaches an apparatus that further comprises a connector member connecting the second portion and the exhaust line (see figure 1).
10. **As to claim 13**, Kremer teaches an apparatus wherein the first channel has a first cross sectional area and the second channel has a second cross sectional area, wherein the second cross sectional area is greater than the first cross sectional area (see figure 1).
11. **As to claim 14**, Kremer teaches an apparatus that further comprises a shoulder formed at the interface of the first and second channels, and wherein the third passageway communicates with the second channel at the shoulder (see figure 1).

12. **As to claim 34**, Kremer teaches an apparatus that further comprises a WYE connector connecting the second inhalation conduit and the exhaust conduit (**see figure 1**).
13. **As to claim 35**, Kremer teaches an apparatus wherein the oxygen intake line and the exhalation conduit are connected to a ventilator (**see abstract**).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims **24-27 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer, Jr. (US 4,803,977).
17. **As to claims 24-27 and 32**, Kremer substantially discloses method steps of transmitting oxygen from a ventilator through a holding chamber and inhalation conduit to a patient during an inhalation sequence of breathing cycle; introducing the medication into the holding chamber **21**; preventing a substantial transmission of an exhaust gas into the holding chamber during an

exhalation sequence of the breathing cycle; transmitting a substantial portion of the exhaust gas into an exhaust conduit 33 during the exhalation sequence; and preventing a substantial transmission of the exhaust gas from the exhaust conduit into the inhalation conduit during subsequent inhalation sequences of subsequent breathing cycles; and transmitting the substantial portion of the exhaust gas from exhaust conduit to the ventilator during the exhalation sequence (see columns 3 and 4).

The method steps would have been obvious because they would have resulted from the use of the device of claim 1; of Kremer.

18. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer, Jr. (US 4,803,977) in view of Walstrom et al. (US 5,178,138).

19. As to claim 5, Kremer substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a one way inhalation valve that comprises a valve member, a valve seat and a blocking member disposed in the second inhalation conduit, wherein the blocking member is spaced downstream from the valve seat, and wherein the valve member is disposed between the blocking member and the valve seat. Walstrom discloses an apparatus that does provide a one way inhalation valve that comprises a valve member, a valve seat and a blocking member disposed in the second inhalation conduit, wherein the blocking member is spaced downstream from the valve seat, and wherein the valve member is disposed between the blocking member and the valve seat (see figure 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kremer's invention by providing a one way inhalation valve that comprises a valve member, a valve seat and a

blocking member disposed in the second inhalation conduit, wherein the blocking member is spaced downstream from the valve seat, and wherein the valve member is disposed between the blocking member and the valve seat as taught by Walstrom in order to have better control of the mixture.

20. **As to claim 6**, Kremer substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a valve member that is a center post valve member connected to the valve seat. Walstrom teaches an apparatus that does provide a valve member that is a center post valve member connected to the valve seat (**see figure 6**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kremer's invention by providing a valve member that is a center post valve member connected to the valve seat as taught by Walstrom in order to have better control of the mixture.
21. **As to claim 7**, Kremer substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a blocking member that has at least one opening formed therein to permit the flow of gases therethrough. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kremer's invention by providing a blocking member that has at least one opening formed therein to permit the flow of gases therethrough as taught by Walstrom in order to have better control of the mixture.

22. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer, Jr. (US 4,803,977) in view of Brooker et al. (US 6,805,118).

23. **As to claim 8**, Kremer substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose the first inhalation conduit comprises an endotracheal tube.

Brooker discloses an apparatus that does provide first inhalation conduit comprises an endotracheal tube (see col. 2 lines 45-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kremer's invention by providing first inhalation conduit comprises an endotracheal tube as taught by Brooker in order to provide accurate amount of medicament.

Allowable Subject Matter

24. Claims 3, 4, 28 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose a second inhalation conduit communicating with the interior space of the chamber housing at the input end, wherein the second inhalation conduit has a second cross sectional area defined substantially perpendicular to the longitudinal flow direction at the input end, wherein the second cross-sectional area is less than the first cross sectional area, wherein the one way inhalation valve is located in the second inhalation conduit, the second inhalation conduit comprising an oxygen intake line communicating with the one way inhalation valve.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772